

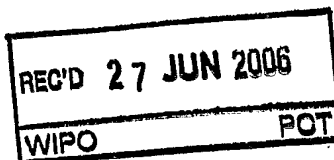
## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 34029/PCT	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US05/03502	International filing date (day/month/year) 04 February 2005 (04.02.2005)	Priority date (day/month/year) 04 February 2004 (04.02.2004)	
International Patent Classification (IPC) or national classification and IPC IPC: Please See Continuation Sheet USPC: 435/188,183,975,91.2,6			
Applicant EPPENDORF AG			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 09 February 2006 (09.02.2006)		Date of completion of this report 11 June 2006 (11.06.2006)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Susan Hanley <i>F. Robert</i> Telephone No. (571) 272-1600	

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/03502

**Box No. I Basis of the report**1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4(a))
  - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-25 as originally filed/furnished
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:
- pages NONE as originally filed/furnished
- pages\* NONE as amended (together with any statement) under Article 19
- pages\* 26-32 received by this Authority on 09 February 2006 (09.02.2006)
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:
- pages 1-17 as originally filed/furnished
- pages\* NONE received by this Authority on \_\_\_\_\_
- pages\* NONE received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US05/03502**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>5, 6 and 35-96</u>	YES
	Claims <u>1-4, 7-34, 97 and 98</u>	NO
Inventive Step (IS)	Claims <u>5, 6 and 35-96</u>	YES
	Claims <u>1-4, 7-34, 97 and 98</u>	NO
Industrial Applicability (IA)	Claims <u>1-98</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and Explanations (Rule 70.7)**

Claims 1-4, 7-34, 97 and 98 lack novelty under PCT Article 33(2) as being anticipated by Rubinsky et al. (WO 92/12722).

Rubinsky et al. disclose the cryopreservation of various biological entities with anti-freeze proteins (AFP). The biological entities include whole cells, enzyme or organs (p. 9, lines 4-14). The AFPs include Type I AFP. AFPs are rich in multiple alanine segments (abstract and p. 23). The solution comprising the AFP and biological entity can also include salts, sugars, glycerol buffers and other reagents known to protect against freeze damage (p. 10, lines 22-29 and p. 31-33). Rubinsky et al. describe the cryopreservation of pig oocytes with the AFP solutions. The oocyte-AFP solutions underwent a freeze-thaw cycle and were evaluated for viability. AFP protected 82.5% of the cells from freeze damage. This disclosure meets the limitations of claims 1 and 2 because enzymes are inherently part of a cell and therefore are present in the claimed composition (p. 38-41). The cellular viability is evidence that the enzymes in the cells retained their activities. Claim 2 is non-limiting because a cell that retains its activity after a freeze-thaw activity is the same as the cell before it was frozen. The freeze-thaw cycles do not change the properties of a viable cell. This disclosure meets the limitations of a kit because a kit is simply a collection of items brought together for a purpose. In the instant case, a cell comprising enzymes in combined with a solution containing an AFP, thus meeting the limitations of the contents of the claimed kit.

Claims 5, 6 and 35-96 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a solution comprising an AFP and an enzyme and a carrier protein such as BSA, a kit thereof or a method of using an AFP to enhance PCR..

Claims 1-98 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation of IPC:

C12N 9/96( 2006.01),9/00( 2006.01);C12Q 1/68( 2006.01);C12P 19/34( 2006.01);G01N 33/53( 2006.01)